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| 10/699,659 | 11/04/2003 | Yi Mei Hsieh Chen | L9079.03107 | 6463 |
| 7590 | 05/22/2008 | | EXAMINER | |
| STEVENS, DAVIS MILLER & MOSHER, L.L.P. Suite 850 1615 L Street, N.W. Washington, DC 20036 | | | FLORY, CHRISTOPHER A | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/699,659 | HSIEH CHEN, YI MEI | |
| | Examiner | Art Unit | |
| | CHRISTOPHER A. FLORY | 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 September 2007.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-22 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

Response to Arguments

1. The §102(b) rejection of claims 1-16,19,20 and 22 as anticipated by Sackner'252 alone has been withdrawn.
2. Applicant's arguments filed 4 September 2007 have been fully considered but they are not persuasive. Claims 21 and 22 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Allison'868. Claims 21 and 22 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by De La Huerga (US Patent 6,346,886). Claims 1-22 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nissila'943. Claims 1-20 and 22 stand rejected under 35 U.S.C. 103(a) as obvious over Sackner'252 in view of Nissila (U.S. 2002/0068873, hereinafter Nissila'873).
3. Applicant repeats the argument that Sackner'252 does not disclose that sensors 42-44 are removably attachable to electrodes 10 and 11, and does not disclose that the garment is washable. However, it is noted that any non-integral component, or one that is merely attached by sewing, clamping, soldering, etc., is inherently removable from other non-integrally constructed components. (*Nerwin v. Erlichman*, 168 USPQ 177, 179.) In this case, the sensors of Sackner'252 are inherently removably attachable to the electrodes for this reason. Likewise, any garment is inherently washable. In paragraph 3 of page 2, Applicant appears to suggest that the removability of the electrodes causes the garment to be washable. It is noted that the two inherent properties are considered independently of one another.

4. In response to applicant's numerous arguments that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Applicant repeatedly makes reference to a "watch-like" body (e.g. page 3, line 1; page 9, line 3; page 11, lines 13 and 20), inductive plethysmographic (IP) sensors (e.g. page 3, line 9; page 5, lines 7 and 20; page 6, lines 6 and 11), a waterproof property which was changed in the last amendment to water fast, and use during sports/athletic/fitness training (page 8), none of which are recited in the pending claims.

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

5. In regards to Applicant's argument that Sackner'252 does not disclose attaching the device to an undergarment, it is noted that a shirt is a type of undergarment and therefore explicitly meets that limitation of the claims.

6. In response to Applicant's argument that Sackner'252 does not disclose use of the device during sports/athletic trainings it is noted first that such use is not recited in the claims. Additionally, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Still further, Applicant admits that Sackner'252 discloses use during normal daily activities (col. 5,

lines 15-31). It is noted that exercise, sport, athletics, and fitness is within the range of normal daily activities of an ambulatory adult.

7. Regarding Applicant's arguments that the impedance plethysmograph measurement of blood flow in Allison'868 is unrelated to measuring a heartbeat signal as recited in the claims, the recitation of the heartbeat has not been given undue patentable weight because the recitation occurs only in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Additionally, it is noted that the measurements of blood flow, cardiac output, and pulse volume all inherently require or relate to measurement of the heartbeat, as evidenced by the Applicant's own characterization of impedance plethysmography sensors throughout the arguments.

Furthermore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

8. Regarding Applicant's arguments against De La Huerga, it is noted that the reference explicitly discloses measurement of the heart beat in column 9, lines 47-97, and further meets all the structural limitations of the rejected claims.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 21 and 22 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Allison (US Patent 4,016,868, hereinafter Allison'868).

11. Claims 21 and 22 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by De La Huerga (US Patent 6,346,886). Particular emphasis is placed on Figures 1, 2 10, 15, 17, 20, 24, 27 and 28 and related paragraphs; as well as column 9, lines 47-67.

12. Claims 1-22 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nissila (US Patent 6,580,943, hereinafter Nissila'943).

Nissila'943 is considered to clearly disclose the claimed invention as evidenced in the Abstract, as well as Figure 4 and the related portions of the disclosure. It is noted that the electrodes are inherently detachable, the monitor capable of being sewn into a garment, and any garment inherently washable.

Claim Rejections - 35 USC § 103

13. Claims 1-20 and 22 stand rejected under 35 U.S.C. 103(a) as obvious over Sackner et al. (U.S. Patent No. 6,551,252, hereinafter Sackner'252) in view of Nissila (U.S. 2002/0068873, hereinafter Nissila'873).

In regards to claims 1 and 22, Examiner Sackner'252 discloses a heart beat signal wireless transmitter (see for example col. 5 lines 66-67 and col. 6 lines 1-11) comprising a body/monitoring garment (1) having at least two sides which construct a modular structure (see for example Figure 5), a PC board carrying a signal transmitter (see for example 42, 43 and 44) for use with ECG data (col. 25 lines 65-67), and a fastening device (41) which is at least on two sides of the body (see for example Figure 5) in which the disclosed zipper is inherently separately connected to the two sides of the body. Examiner takes the position that the fastening device (41) could obviously be substituted with the tightening/clamping device (8), since both provide a fastening/securing purpose (see for example col. 15 lines 23-49 and col. 25 lines 46-56).

Further in regards to claims 1 and 22, Sackner'252 also discloses multiple detachable sensor bands/belts (see for example 4, 5 and 6) which are connected to different sides of the body through the fastening device (see Figure 5), and further comprises a sensor component which comprises conductive material for transmitting ECG signals (col. 25 lines 56-58), and is also in electrical connection with the PC boards (see element 45). Notwithstanding the position that the sensor bands are disclosed as detachable, such a property is inherent to any non-integrally formed component, or alternatively it would have been obvious to one having ordinary skill in the art at the time of the invention to have detachable belts, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicnman*, 168 USPQ 177, 179.

Also in regards to claims 1 and 22, although the Sackner'252 reference does not specifically disclose that the fastening bands/belts are made of a water fast material, it is understood that water fastness, which denotes only a resilience or resistance to water, is an inherent property of those materials disclosed as the garment, straps and electrodes of Sackner'252, since all articles worn by humans must be in some manner resilient to water so as not to degrade by contact with moist human skin or perspiration. Alternatively, the Nissila'873 reference teaches that it is well known in the art to use waterproof materials for devices that provide heart beat signal measurements and transmitters (see for example paragraphs 11 and 19). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Sackner'252 to include waterproof materials to protect the system's water-sensitive components as taught by Nissila'873. Herein, it is noted that a waterproof material, which is impervious to water, is inherently also water fast, or resilient to water.

In regards to claim 2, Examiner takes the position that the flexible sensor bands (4, 5 and 6) as taught by Sackner'252 are inherently made of both a conductive and nonconductive/elastic materials (see for example col. 14 lines 59-62 and col. 25 lines 56-58), whereas the elastic materials are used for providing longitudinal elasticity sufficient to retain the band against the body. In the alternative, Examiner takes the position that it is well known in the art for sensors/electrodes to be made of both a conductive and nonconductive fabric.

In regards to claims 3-4, Sackner'252 teaches that the sensor bands are flexible and conductor, which is interpreted as meeting the limitations of compounds with conductive fiber and electronic fiber.

In regards to claims 5-8 and 19, Examiner takes the position that the system as taught by Sackner is capable of being fixed to underwear, including underwear to be worn on the torso, by sewing (see for example col. 14 lines 65-66 and Figure 5).

In regards to claims 9-10, Sackner'252 discloses that various fastening devices are interchangeable, including a buckle assembly and a zipper (see for example elements 8, 32 and 41, col. 14 lines 18-28 and col. 15 lines 41-47), and since the devices provide the same function it would have been obvious to one having ordinary skill in the art to modify an embodiment taught by Sackner'252 to include any of the fastening devices in the instant claims. Similarly in regards to claims 11-16, Examiner takes the position that the Sackner'252 reference teaches of a clamp comprising a clamping plate and tooth grip piece (see for example col. 14 lines 17-29 and col. 15 lines 41-47).

In regards to claims 17-18, Sackner'252 does not specifically teach of the use of male connecting heads and female connecting holes. However, Nissila'873 teaches that it is well known in the art to use male connecting heads and female connecting holes for electrical connection purposes (paragraph 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Sackner'252 to include male connecting heads and female connecting holes

as taught by Nissila'873, since this type of connection is well known in the art for providing and electrical connection, as taught by Nissila'873.

In regards to claim 20, Examiner acknowledges that the Sackner'252 reference does not specifically teach of having one electrode be a negative electrode and another electrode being a positive electrode. However, it is an inherent property of any electrical monitoring system to have one electrode more positive or negative in reference to the other electrode of the pair so that a measurement can be taken.

Alternatively, Examiner takes the position that it is inherent in the system as taught by Nissila'873 that one of the two electrodes (402 and 404) would be positive and the other would be negative, since this would be required to complete the circuit, and would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Sackner'252 (see for example Figure 3), to include a positive and negative electrode to provide a complete circuit.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory
21 May 2008

/George Manuel/
Primary Examiner